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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,399	09/27/2000	Masao Washizu	001268	7255

23850 7590 10/04/2002

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EXAMINER	
BROWN, JENNINE M	
ART UNIT	**PAPER NUMBER**
1743	4

DATE MAILED: 10/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/670,399	WASHIZU ET AL.	
	Examiner	Art Unit	
	Jennine M. Brown	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *4* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 11-13, drawn to Kit for Measuring a Component in a Sample, classified in class 436, subclass 808.

II. Claims 1-10 and 14-23, drawn to Method for Separating a Complex Substance Using an Electrode, classified in class 204, subclass 450.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as protein separation whereas invention II can be used for DNA sequencing. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Donald W. Hanson on 09/25/2002 a provisional election was made without traverse to prosecute the invention of Invention I, claims 1-10 and 14-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Donald W. Hanson on 09/25/2002.

The application has been amended as follows:

Claims 11-13 have been deleted.

Claim Objections

Claim 15 is objected to because of the following informalities: "comprisis" should be "comprises". Appropriate correction is required.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Regnier, et al. (US 5958202).

Regarding claims 1-3 and 8, Regnier, et al. teach a method of forming a complex substance to separate out a specific molecule from a mixture by applying a dielectrophoretic field (col. 1, l. 29-33) then detection to give qualitative measurement of the separated specific molecule (col. 1, l. 33-50) where the application deals with separation of proteins, nucleic acids and cells (col. 1, l. 29-33).

Regarding claims 4-6 and 7-10, Regnier, et al. teach a method of forming a tethered complex (e.g. coated bead or channel) which is bound to the specific molecule (e.g. substrate or antibody) but not bound to the (e.g. enzyme or antigen) complex substance which then binds to the tethered specific molecule (coated bead or channel

with substrate or antibody) complex substance, separated out by dielectrophoresis and detected to get a qualitative measurement of the specific molecule where the application is specifically related to enzyme labeled antigen (col. 9, l. 26 – col. 10, l. 10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regnier, et al. (US 5958202).

Regnier, et al. teach some mixing of solutions to be detected may have to be done at high potential for a method of forming a complex substance to separate out a specific molecule from a mixture by applying a dielectrophoretic field then detection to give qualitative measurement of the separated specific molecule previously formed by a

tethered complex (e.g. coated bead or channel) bound to the specific molecule (e.g. substrate or antibody) but not bound to the (e.g. enzyme or antigen) complex substance which then binds to the tethered specific molecule (coated bead or channel with substrate or antibody) complex substance.

Regnier, et al. do not specifically teach the voltage range of 500 KV/m. It would have been obvious to one of ordinary skill in the art to determine, through routine experimentation the optimum voltage range to pulse around the sample to mix it properly so that binding occurs and detection of the complex will occur. It is known in the art to vary any one of the result-effective parameters to optimize separation. Clearly voltage is a result-effective parameter.

Relevant Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6221654 teaches a method and apparatus for analysis and sorting of polynucleotides based on size using an electrophoretic apparatus.

US 6133436 teaches a method and apparatus for bonding biomolecules to solid support beads and separation based on the affinity of the biomolecules for the modified support layer on the beads.

US 6080556 teaches an amino acid antigen antibody method of separation with quantitative results using slab gel electrophoretic apparatus.

US 5585248 teaches a method for assaying activity of oxidase activating enzyme with amino acid residue for separation and quantitation using liquid chromatography.

US 6171865 teaches simultaneous analyte determination and reference balancing using electrophoretic sensing devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (703) 305-0435. The examiner can normally be reached on M-F 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

jmb
October 1, 2002

Jill Warden
Supervisory Patent Examiner
Technology Center 1700